

REMARKS

Claim 33 has been cancelled, and claims 68-75 have been added to this application. Thus, claims 34-58 and 60-75 are now pending in this case.

Double Patenting

The filtering face mask of the present invention includes an exhalation valve that has a valve seat and a single flexible flap. The flexible flap has a stationary portion and one free portion. The one free portion is disposed beneath the stationary portion when the flexible flap is worn on a person. The exhalation valve also comprises a valve cover that is disposed over the valve seat and comprises a surface that holds the flexible flap against a flap-retaining surface on the valve seat.

As the Examiner is aware, a double patenting rejection can only be sustained if the applicant is claiming the same invention that is being claimed in another patent application or if the applicant is claiming an invention that would have been obvious in view of an invention that is being claimed in another patent or patent application. In making this double patenting rejection, the Examiner has not indicated whether the rejection is a double patenting rejection under 35 USC § 101 or whether it is a double patenting rejection that has been made under the judicially-created doctrine of obviousness type double patenting. Applicants request that clarity be provided to record in this regard.

Because none of the claims that are pending in this case are identical to the claims in any of applicants' copending applications or issued patents, applicants will presently assume that the double patenting rejection has not been made under 35 USC § 101.

Thus, turning to the judicially-created doctrine of obviousness-type double patenting, applicants respectfully submit that a double patenting rejection of this kind cannot be sustained because no evidence has been presented, which shows that appellants' claimed invention is obvious over the invention claimed in any of appellants' issued patents or allowed patent applications. As the Examiner is aware, obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. This type of rejection is made when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly-owned patent.¹ The purpose of the doctrine is to prevent an unjustified extension of the

¹ *In re Bratt*, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991).

patent term by allowing a second patent that claims an obviousness variant of the same invention.² Generally, a "one-way" test has been applied to determine whether an obviousness-type double patenting rejection can be sustained. Under this test, the Examiner must ascertain whether the application claims are obvious over the patent claims.³ If the application claims are patentably distinct from the claims in the patent, then the double patenting rejection is not proper and must be withdrawn. If, however, the application is not patentably distinct, then the applicant can file a Terminal Disclaimer to eliminate the issue with respect to double patenting.⁴

In this application, the Examiner has yet to identify any claim in any of applicants' patents (or any copending application), which requires a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface. Because this feature is not also claimed in any of applicants' copending patent applications, the obviousness-type double patenting rejection cannot be sustained. Accordingly, it is incumbent upon the Examiner to identify where applicants are claiming an exhalation valve that has its flexible flap secured to a flap-retaining surface on a valve seat in this manner if the double patenting rejection is to be sustained. In the absence of putting this evidence into the record, the double patenting rejection must be withdrawn.

In any case, the Examiner has not allowed any claims in any of applicants' copending applications. Until such claims have been allowed and those claims have issued, the double patenting rejection is premature. Applicants cannot terminally disclaim subject matter over a patent application, which may never issue as a patent. Thus, any double patenting rejection can only be made provisionally. Please see MPEP § 804 I.B., 800-19 (August 2001).

Obviousness Rejection

Claims 33-36, 50-56, 58, and 60-67 have been rejected under 35 USC § 103 as being unpatentable over British patent GB 2,072,516A to Simpson et al. (Simpson) in view of U.S. Patent 1,701,277 to Shindel. Applicants respectfully submit that this rejection cannot be sustained for a number of reasons.

² *In re Goodman*, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993).

³ *In re Berg*, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

⁴ *In re Berg*, 46 USPQ2d at 1229.

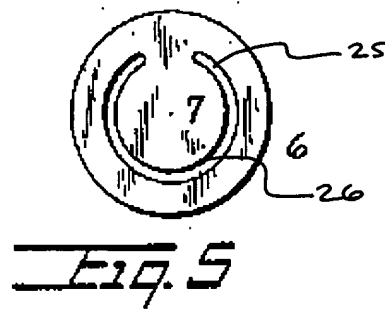
Firstly, neither Simpson nor Shindel discloses a *flexible flap that is pressed towards a seal surface under any orientation of the valve*. An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of Simpson does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer is neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A) that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

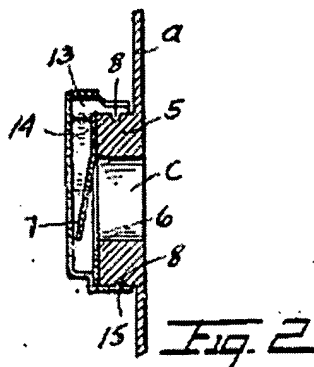
Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. The flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity, however, cannot hold the flexible flap against the flap-retaining surface in an abutting relationship with it when a fluid is not passing through the orifice under any orientation of the filtering face mask.

Shindel also does not teach or suggest a structure that would cause the flexible flap to be pressed against a seal surface. Shindel's flap has a rim portion 6 that surrounds the movable portion of the flap 7:

⁴ *In re Berg*, 46 USPQ2d at 1229.



A cut-out, identified by applicants' attorney using number 25 is provided in the flap. Because Shindel's flap is mounted flat on a circular boss 5 and because Shindel's valve seat is in direct alignment with the point of mounting, Shindel does not present a structure that would cause flap 7 to be pressed towards the seal surface in an abutting relationship with it under any orientation of the valves:



Like Simpson, Shindel's flap would at best merely reside flush against the seal surface. In addition, Shindel describes a flap 7 that is different from applicants' flap in that it does not include a stationary segment on its peripheral edge. The cut-out 25 shown above in Fig. 5 only defines a peripheral edge (identified by applicants' attorney using numeral 26) that has a free segment. This is because Shindel's peripheral edge does not extend fully about the out edge of the flap 7.

Secondly, the record lacks any evidence that a person of ordinary skill would have combined the teachings of Simpson with those of Shindel. Simpson's Figure 2, which is reproduced below, shows a flange, (identified by applicants' attorney using numeral 27) that holds the flap against a flap-retaining surface on the valve seat:

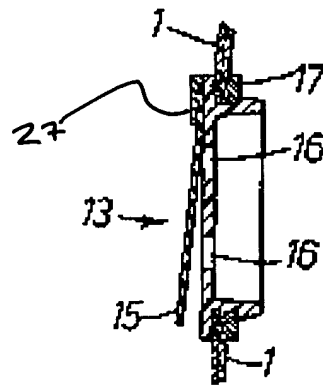


FIG. 2.

Because Simpson uses this system for securing its flap to the valve seat, there is no reason why a person of ordinary skill would have been motivated to use a surface on a valve cover to hold the flexible flap against the flap-retaining surface on the valve seat. Although the Examiner indicates that "[i]t would have been obvious to modify the manner of attachment of the exhalation valve of Simpson et al. to provide a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel." **This statement only expresses a reason why a person of ordinary skill might have used a valve cover on the Simpson valve. It does not provide any evidence as to why a person of ordinary skill would have been motivated to use a valve cover that comprises a surface that holds the flap against the flap-retaining surface.** Until the Examiner can put such evidence in the record, the combination of Simpson and Shindel cannot be properly sustained. The Examiner's attention is directed to *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002) where the Federal Circuit carefully explained the requirements for combining references. In so doing, the Court made clear that references cannot be combined without evidence that demonstrates why the teachings from two separate references would have been combined.⁵

Fourthly, the Simpson and Shindel documents each present very good evidence of a lack of motivation to combine their respective teachings, Shindel's technology was known to persons of ordinary skill long before the Simpson publication, yet Simpson did not employ the Shindel

⁵ See, *Lee*, 61 USPQ2d at 1433 ("The factual inquiry whether to combine references must be thorough and searching." It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.").

technology in its flapper-style exhalation valve. If the use of the particular structure necessary for holding the flap against the flap-retaining surface and causing it to be pressed towards the seal surface under any orientation would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. But a very long time has passed since Shindel's publication in 1929 and its disclosure of a valve device for a respirator, and its technology nonetheless did not find its way into a Simpson-type structure over this large time span. If Shindel's technology provided benefits to the Simpson structure, you would have expected the skilled artisan in the respirator art to have employed it by the time of Simpson's publication. A prolonged existence of unused technology provides very good evidence of nonobviousness.⁶ Simpson (published about 52 years after Shindel and filed more than about 12 years before the effective filing date of the present application) also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the long time that has elapsed since Shindel's publication, and the failure to use this technology in a Simpson-type flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.⁷

Fifthly, Simpson and Shindel do not teach or suggest the benefits that can be provided by applicants' invention. The flapper-style valve of applicants' invention can open easily in response to exhalation pressure but also can be pressed towards the seal surface to prevent the influx of contaminants through the valve when a wearer is not exhaling. Applicants' valve flap thus can remain closed under a variety of orientations to prevent contaminants from entering the mask interior. Applicants achieve this through the use of a single flexible flap that has one free portion,

⁶ See *Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

one stationary portion, and a peripheral edge, where the peripheral edge has a stationary and free segments which are associated, respectively, with the stationary and free portions of the flap, and through use of a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve. Neither the Simpson flap nor the Shindel flap is capable of being pressed against the seal surface so as to remain substantially closed under any orientation of the mask. Because neither prior art flap is prestressed, each flap would droop open when the wearer tilts their head downward. Simpson recognizes this problem and addresses it by placing its valve on the top portion of its pouch-shaped mask. Simpson, therefore, uses gravity to hold the flap closed when the wearer is not inhaling. The Simpson approach, nonetheless, is still problematic in that a flap can be separated from the seal surface when the wearer tips their head substantially downward. Shindel does not appear to deal with the issue at all. The failure of both of these documents to provide any appreciation for the benefits that are achieved through applicants' invention, further establishes the nonobviousness of their invention.⁸

Sixthly, the copying of the technology of the present invention shortly after its publication further establishes the non-obviousness of the present invention. In a number of cases, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.⁹ For example, in *Specialty Composites v. Cabot Corporation*,¹⁰ the Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain,

⁷ *In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

⁸ See, e.g., *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

⁹ See e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 622, 2 USPQ2d 1350, 1355 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 849 (1987) (the conclusion that the claimed invention would not have been obvious is supported by evidence of commercial success and acts of the infringer in trying but failing to "develop the claimed invention and [then copying] it instead"); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

¹⁰ 6 USPQ2d 1601, Fed. Cir. 1988.

is indicative of unobviousness."¹¹ As the Examiner is aware, secondary considerations like copying must always be considered in connection with an obviousness determination.¹²

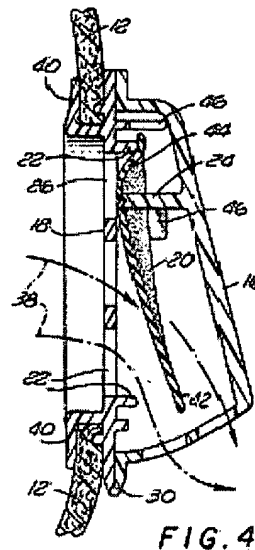
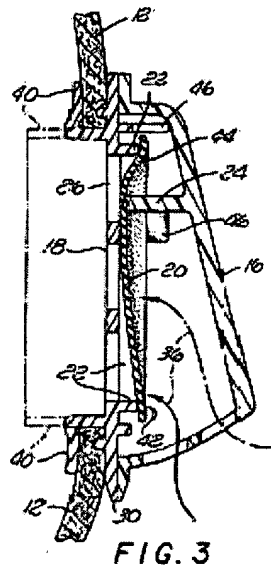
Moldex Metric, for example, introduced a valve product in 1998, a sample of which is attached to this Amendment as Exhibit C. If you examine the Moldex product, you will see that it has a valve cover that has a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in a substantial abutting relationship under any orientation of the valve. In fact, U.S. Patent 6,047,698 to Magidson et al. was filed on August 20, 1998, after appellants' invention was publicly disclosed. If you look at Moldex' work prior to the effective filing date of the present case, you will see that Magidson's filtering face mask work included button-style valves (see U.S. Patent 4,873,972). But the more recent '698 Magidson patent (which describes the Exhibit C sample) states the benefits of using the technology claimed in this patent application:

The valve member 16 includes an off center arm 24 which cooperates with a shelf portion 26, located within the valve seat 22, to lock the flexible flap 20 off center in position within the valve 14 when the two half members 16 and 18 are closed, as shown by arrow 28, around a hinge portion 30.

(Column 2, lines 15-21). The '698 Moldex patent goes on to state that the flap is pushed into sealing engagement with the valve seat when a fluid is not passing through the orifice. Moldex illustrates the technology in Figs. 3 and 4:

¹¹ *Id.* at 1608.

¹² *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).



Another product of similar structure, which also was introduced after the publication of applicants' invention, is shown in Exhibit D. This mask product is sold by Survivair.

The use of the technology of appellants' invention by other respiratory product manufacturers after publication of applicants' invention provides very good evidence that their invention would not have been obvious to a person of ordinary skill. Although Simpson's and Shindel's teachings had been known for many years before applicants' filing date, there is no evidence that any competitor had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of such products after the publication of the technology of applicants' invention, however, further establishes that person's skilled in the filtering face mask art surely did not find obvious the subject matter of applicants' invention.

In short, applicants' invention would not have been obvious to a person of ordinary skill because the primary reference to Simpson fails to teach or suggest a number of the basic elements of applicants' invention. Simpson does not have the flap held against a flap-retaining surface by pressure from a surface on the valve cover. Simpson's flap is not even pressed against the seal surface. Simpson therefore places its exhalation valve on the top portion of its pouch-shaped mask so that gravity can keep the flap closed under neutral conditions. In this position, however, Simpson's valve can fog the wearer's eyeglasses, and it cannot take the best advantage of the momentum of the exhaled airflow to open the valve. Further, the record is devoid of any teaching, suggestion, or motivation to combine the teachings of Simpson and Shindel. Indeed, Simpson and

Shindel present very good evidence for a lack of motivation to combine their teachings because Simpson already has its flap mounted suitably to the valve seat by a different method. But even if the references would have been combined by a person of ordinary skill, Shindel does not teach how to get the flap to be pressed against the seal surface under neutral conditions and any orientation of the valve. And even if Shindel did disclose all the features missing in Simpson, Shindel's technology was never mentioned in Simpson or any other exhalation valve document despite it being known for many years. These two documents also do not teach or suggest the benefits that applicants' invention may provide. Further, the copying of the technology claimed in the present application by competitors, after this publication of applicants' invention, also establishes that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

Finally, even if we make the grand assumptions that the record does suggest that a person of ordinary skill would have been motivated to use Shindel's valve cover and means for securement in Simpson, and if we then totally ignore the nonobvious evidence with respect to (a) the long time passing since Shindel's publication and (b) the copying of applicants' technology, the record nonetheless is still devoid of any teaching or suggestion for having the flexible flap pressed towards the seal surface in a substantial abutting relationship. The Examiner has yet to identify any reference that teaches or suggests any structure capable of providing this feature which is suggested for use in a non-centrally mounted flapper-style exhalation valve. **The Examiner states on page 3 of the Office Action that Simpson discloses this feature, and cites page 2, lines 37-50 of Simpson for this disclosure, but applicants find no such teaching at that location in the Simpson patent.** To the contrary, this portion of the Simpson patent merely indicates that the flap covers the valve opening 16 during an inhalation. It does not indicate that the flap is pressed towards the seal surface when a fluid is not passing through the orifice. Applicants urge the Examiner to reconsider this position, particularly in light of the Castiglione and Bowers Affidavits and Declarations, respectively. If the Examiner maintains the view that Simpson discloses a flap that is pressed towards the seal surface, applicants request that clear **evidence** or sound explanation furnished to the record.

As the Examiner is aware, the reviewing courts have stated on numerous occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.¹³ The MPEP is in accord:

Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient.¹⁴

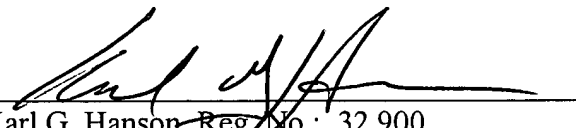
If the Examiner chooses to continue down this path, appellants request that he furnish the record with an affidavit that shows why his view is valid over Castiglione and Bowers.

For the above reasons, the rejection under 35 USC § 103 cannot be properly sustained. Please favorably reconsider the double patenting rejection and obviousness rejections.

Respectfully submitted,

June 24, 2002
Date

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¹³ See, *In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); see also *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

¹⁴ MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

34. (amended) The filtering face mask of claim [33] 68, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

36. (amended) The filtering face mask of claim [33] 68, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

37. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap would normally assume a flat configuration when no forces are applied to it but has a curved profile when viewed from a side elevation.

40. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

42. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap is made from a crosslinked polyisoprene.

43. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap has a Shore A hardness of about 30 to 50.

44. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

47. (amended) The filtering face mask of claim [33] 68, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

50. (amended) The filtering face mask of claim [33] 68, wherein the stationary [portion] segment of the peripheral edge of the flexible flap includes about 10 to 25 percent of the total [circumferential] peripheral edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

51. (amended) The filtering face mask of claim [33] 68, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body, and wherein the flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

52. (amended) The filtering face mask of claim [33] 68, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

53. (amended) The filtering face mask of claim [33] 68, wherein the mask body is cup-shaped and comprises (1) at least one shaping layer for providing structure to the mask, and (2) a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

54. (amended) The filtering face mask of claim [33] 68, wherein a high percentage of the exhaled air is purged through the exhalation valve.

55. (amended) The filtering face mask of claim [33] 68, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

58. (amended) The filtering face mask of claim [33] 68, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

60. (amended) The filtering face mask of claim [33] 68, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

61. (amended) The filtering face mask of claim [33] 68, wherein the valve cover has an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation.

66. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

- (i) a seal surface;
- (ii) an orifice that is surrounded by the seal surface; and
- (iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front[, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice]; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface, wherein the flexible flap is held against the flap-retaining surface and is positioned relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith under any orientation of the valve when a fluid is not passing through the orifice.